UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,891	10/15/2003	Amir J. Tehrani	RMXLNZ00100	7544

40518 7590 05/04/2012

LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER	
ALTER, ALYSSA MARGO	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
05/04/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,891	TEHRANI, AMIR J.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *123,126,141,149-152 and 159* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *123,126,141,149-152 and 159* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-13-12 & 2-13-12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 13, 2012 has been entered.

Response to Arguments

2. Applicant's arguments filed February 13, 2012 have been fully considered but they are not persuasive. The Applicant argues that Scheiner et al. initiates a respiratory cycle and does not supplement a breath (see page 5 of Remarks). However, as previously made of record, Scheiner et al. discloses the method illustrated in FIG. 4 that delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level. The stimulation is therefore considered to elicit a diaphragm response and "supplement a breath". The stimulation supplements a breath, but increasing inspiration until the diaphragm response yields a sufficient value for the minute ventilation.

3. The Applicant additionally argues that Scheiner et al. does not stimulate with “an” electrical signal (see page 6 of the Remarks). “in Scheiner, stimulation once and if there is no response by the diaphragm, increasing the voltage and stimulating again would represent two electrical stimulation signals, not an electrical stimulation signal", as

claimed. This would not meet or make obvious the representation of an electrical stimulation signal comprising a burst or series or pulses" (page 6). The examiner respectfully disagrees.

4. Scheiner et al. does not disclose two separate stimulation signals being delivered to the patient at one time. Scheiner et al. merely discloses delivering one signal, and if the signal does not yield appropriate results, modifying the signal same signal and delivering it again to the patient. Scheiner et al. does in fact disclose the delivery of "a electrical signal" and does not delivery multiple signals to the patient at one time.

5. Finally, the Applicant argues that Scheiner et al. or Park does not disclose providing stimulation during inspiration. However, as previously stated, Scheiner et al. delivers stimulation to supplement a breath by increasing inspiration until the diaphragm response yields a sufficient value for the minute ventilation. Likewise, Scheiner et al. necessarily provides the stimulation during the inspiration portion to provide a modification to minute ventilation.

6. Therefore, the claims remain rejected under Scheiner et al. in view of Park as indicated below.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 123, 126, 141, 149 -152 and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183 B1) in view of Park (US Patent Publication 20030153954 A1).

9. Scheiner et al. discloses a diaphragmic pacing system that monitors patient respiratory activity and delivers an electrical stimulus to the phrenic nerve. “Tip electrode 121 and ring electrode 122 can be used for sensing respiratory activity by a method such as minute ventilation… and/or for delivering diaphragm therapy by delivering an electric stimulus to phrenic nerve 102”(col. 3, lines 39-44). The electrodes sense respiratory activity and thus sense “respiration”.

10. As depicted in figure 4, “in block 404, the present method analyzes whether the diaphragm responded to the therapy delivered in block 303. This can be done by analyzing the signal representing respiratory activity shortly after the therapy is delivered. If it is determined in block 404 that the diaphragm did not respond to the therapy, then the voltage pulse level is increased in block 405. The method illustrated in FIG. 4 delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level. The electric stimulus is delivered by the output circuit via the lead to the electrode to the phrenic nerve” (col. 7, lines 49-60). Therefore, the stimulation parameter (i.e. voltage) is “incrementally adjusted until the breathing cycle is further adjusted to reach the desired level". Furthermore, since the minute ventilation is increased to a desired level, the “inspiration duration" and “inspiration volume” also be increased.

11. Thus, Scheiner et al. discloses in method illustrated in FIG. 4, that delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level. The stimulation is therefore considered to elicit a diaphragm response and "supplement a breath". Thus the stimulation supplements a breath, but increasing inspiration until the diaphragm response yields a sufficient value for the minute ventilation. Likewise, Scheiner et al. necessarily provides the stimulation during the inspiration portion to provide a modification to minute ventilation.

12. Scheiner et al. monitors for threshold change to determine Cheyne-Stokes respiration (col. 7, lines 16-18). Scheiner et al. discloses the device substantially as claimed but does not specifically recite the creation of an “intrinsic baseline profile”. Park et al. teaches the use of a baseline respiration comparison to determine if Cheyne-Stokes respiration is occurring in a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the determination of Cheyne-Stokes respiration as disclosed by Scheiner, with the baseline comparison for determining Cheyne-Stokes respiration as disclosed by Park et al. since such a modification would provide the predictable results of enabling a medical technician to monitor the progression of the patient and confirm the presence of Cheyne-Stokes respiration. By having a baseline visually displayed a physician or technician can observe and confirm the diagnostic assessment.

13. As to claim 141, since the device provides stimulation to increase the minute ventilation and provide respiratory therapy to the patient, the stimulation elicits an

inspiration rate different from the inspiration rate (i.e., increases from intrinsic respiration until a threshold value is met).

14. As to claim 149, Scheiner et al. discloses the treatment of patients with Cheyne-Stokes respiration. Cheyne-Stokes respiration is a pattern of breathing with gradual increase in depth and sometimes in rate to a maximum, followed by a decrease resulting in apnea. Since Scheiner et al. provides stimulation therapy and treatment for patients with Cheyne-Stokes respiration (i.e. breathing with increased depth and rate), Scheiner obviously provides stimulation to "elicit a slow elongated inspiration" in order to counter the Cheyne-Stokes respiration of increased depth and rate.

15. As to claim 151, “the exact pulse level/threshold for stimulation of the phrenic nerve is determined during implantation, and it is desired to keep the level as low as possible to save batter power and provide patient comfort” (col. 7, lines 1-5). Therefore the stimulation delivered by Scheiner et al. is “low level sequential stimulation” in order to preserve battery power.

16. As to claim 152, providing stimulation to enhance the patient’s respiration will obviously manipulate blood gases.

17. As to claim 159, as depicted in Scheiner et al. figure 4, once the breathing reaches a desired level, stimulation is ceased and the system returns to monitoring respiration.

18. As to claim 150, the modified Scheiner et al. discloses the device substantially as claimed but does not explicitly disclose delivering stimulation to “elicit a fast, short inspiration”. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify the stimulation to enable the patient to execute fast, short inspiration in order to provide the predictable results of modifying the stimulation treatment to meet specific patient therapeutic needs and requirements to mitigate a variety of breathing disorders such as hypoventilation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762